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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,313	03/04/2002	Christine Dingivan	10271-063-999	7146
20583	7590	06/09/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SKELDING, ZACHARY S	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/091,313		DINGIVAN, CHRISTINE	
	Examiner		Art Unit	
	Zachary Skelding		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Applicant's species election in the reply filed April 10, 2006 is acknowledged.
2. Claims 1-71 are pending.
3. Upon reconsideration, the previous Restriction Requirement (mailed March 10, 2006) has been **VACATED**. The following new Restriction Requirement is set forth. The Examiner apologizes for any inconvenience to Applicant in this matter.
4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-69 drawn to a method of treating an autoimmune disorder, classified in Class 424, subclass 130.1.
 - II. Claims 70 and 71 drawn to a kit comprising MEDI-507 antibody, Class 435, subclass 810.
5. Groups II and I are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process. The antibody of Group II can be used for affinity purification and detection assays.

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Species Election

6. This application contain claims directed to the following patentably distinct species of the claimed invention:

7. If applicant elects Group I, applicant is required to elect one species, and additional sub-species if required, from **each** of groups A-D:

A. “autoimmune disorder or inflammatory disorder”

Applicant is required to elect one “autoimmune disorder or inflammatory disorder”, such as from the “autoimmune disorders” and “inflammatory disorders” disclosed in the instant specification at pages 25-27, e.g., “psoriasis” or “septic shock”.

The “autoimmune disorder or inflammatory disorder” species are patentably distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Further, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

AND

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B. one or more “CD2 binding molecules” AND first and second “CD2 binding molecules”

Applicant is required to elect,

i. ONE CD2 binding molecule, for prosecution on the merits of the claims reciting one or more “CD2 binding molecules” (e.g. claim 4),

OR

ii. TWO CD2 binding molecules, for prosecution on the merits of the claims reciting first and second “CD2 binding molecules” (e.g., claim 8).

Thus, an example election might be “**anti-CD2 antibody**” (as disclosed in the instant specification, paragraph bridging pages 56-57), **OR**, for example, “**anti-CD2 antibody**” as the first CD2 binding molecule and “**LFA3TIP**” (as disclosed in claim 24) as the second CD2 binding molecule.

The “CD2 binding molecule” species are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Further, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

AND

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C. “additional agents”

Applicant is required to elect a single disclosed species of “additional agent” wherein the additional agent is selected from the group comprising:

- i. An immunomodulatory agent,
- ii. A dermatological agent,
- iii. An anti-angiogenic agent or
- iv. An inflammatory agent.

Furthermore

- a) If i) is elected, applicant is further required to **elect a single “immunomodulatory agent”** species, for example from those disclosed in the instant specification, page 92, 2nd paragraph to page 93, 1st paragraph, such as **“cyclosporine A”; OR “cM-T412”** (an anti-CD4 antibody/T cell receptor modulator); **OR “the extracellular domain of a TNF- α receptor or fragments thereof”**.
- b) If ii) is elected, applicant is further required to **elect a single “dermatological agent”** species, for example, from those recited in claim 42, such as **“tazarotene”**.
- c) If iii) is elected, applicant is further required to **elect a single “anti-angiogenic agent”** species, for example, from those recited in the paragraph bridging pages 96 to 97 of the instant specification, such as **“anti-VEGFR antibodies”**.
- d) If iv) is elected, applicant is further required to **elect a single “anti-inflammatory agent”** species, for example, from those recited in claim 65, such as **“aspirin”**.

The “additional agent” species are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Further, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

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8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of inventions unpatentable over the prior art, the evidence of admission may be used in rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.

Patent Examiner

June 1, 2006

Phillip Gambel
PHILLIP GAMBEL, PH.D. JD.
PRIMARY EXAMINER

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